

### REMARKS

Entry of the foregoing amendments, and reexamination and reconsideration of the subject application, and in light of the following remarks, are respectfully requested.

The courtesy of the telephonic interview with the examiner and his supervisor on June 1<sup>st</sup> is gratefully appreciated.

#### Amendments

Claim 1 has been amended to incorporate the description at page 7 (first and second paragraphs), regarding the hardness of the composition.

Claim 2 has been amended to include the language at page 8 (line 10) that the treatment administers the composition between the hyponychium and the nail plate to reside in contact with the nail bed.

No new matter is presented.

#### Rejections under 35 U.S.C. 112, first paragraph

As discussed during the interview, the Stedman's Medical Dictionary is incorrect; the hyponychium is at the distal part of the nail, opposite the cuticle.

Regarding the rejection of claim 6, applicant has a right to retreat in the breadth of his claim to avoid the prior art and recite what is not being claimed. *In re Johnson and Farnham*, 194 USPQ 187, 196 (CCPA 1977).

Accordingly, these rejections should now be withdrawn.

#### Rejections under 35 U.S.C., second paragraph

The rejection of claims 1, 9-12, and 14 does not show that one of ordinary skill in the art could not reasonably determine what is being claimed, especially as claim 1 is now amended. *In re Venezia*, 189 USPQ 149 (CCPA 1976) ("kit" not indefinite). There is no prohibition against functional terminology in a composition or article of manufacture claim, and the claim merely defines the invention in regard to a certain function. *In re Swinehart*, 169 USPQ 226, 229 (CCPA 1971).

The present amendment to claim 1 clarifies that the composition is functional in the method recited in claim 2. The composition is defined in the claim as "semisolid" and not as a solid (in comparison with a medical plaster, an example of a solid).

Digging one's finger nail(s) into a bar of soap is a common experience. All the second paragraph of §112 requires is that one of ordinary skill in the art understand the metes and bounds of the invention being claimed, *not* whether the claim is enabled. The language of claim 1, including the functional language, is readily understood in this context and in light of the disclosure at page eight of the specification. Accordingly, this rejection should now be withdrawn. Regarding enablement, nothing more than routine experimentation is needed to vary the hardness of a material and determine whether, by scratching or rubbing, as described in the specification and specifically recited in claim 1, it can be forced between the hyponychium and the nail plate and past the hyponychium to be in contact with the nail bed.

#### Rejection under 35 U.S.C. §102

The rejection of claims 1 and 9-11 as anticipated by Maibach is respectfully traversed in light of the present amendment.

Maibach discloses compositions like lotions, creams, pastes, and ointments which common experience indicates do not meet the hardness limitations of the claim. The "plaster" (col. 4, ln. 8), if it is like plaster used for casts infused with an antifungal ingredient, is, like the lotions etc., "intended for long-term adhesion to the body surface" (col. 4, ln. 11-12). A plaster is also not a semisolid, and scratching it will not cause any portion of the plaster to deform and be forced between the nail plate and hyponychium. Maibach uses the same prior art formulations (col. 4, ln. 8-10) in the claimed invention (col. 14, ln. 27-30). While some consider gels and lotions to be semisolid (e.g., col. 15, ln. 17 and 26), such semisolids are not sufficiently hard to be scratched (let alone scratched to force a portion past the hyponychium).

Accordingly, Maibach does not anticipate claim 1. Neither would claim 1 have been obvious from Maibach because the method of administration in that

invention is to create an opening orthogonal to the nail bed and apply a covering for long-term use. Examples 4-6 describe antifungal patches applied to patients' nails, some after "a curette is [ ] used to scrape nail debris from the nail bed at a site as close to the cuticle as possible" (col. 22, ln. 19-21). Because Maibach physically removes the barrier to the nail bed, the nail plate, any formulation that will remain in contact with the open area is suitable, and so Maibach uses occlusion (tape, skin patch, plaster) to keep the medication in contact with the nail bed. Because the present method requires overcoming the hyponychium barrier, though not as tough as the nail plate, the composition must be sufficiently solid to breach the barrier, and also sufficiently liquid to be deformed by scratching or rubbing; hence a semisolid. Maibach describes nothing appreciative of the hardness (or viscosity, since it is a semisolid) of an antifungal formulation needed to breach the hyponychium. Accordingly, claim 1 is allowable over Maibach and the rejection should now be withdrawn.